ACHILLION PHARMACEUTICALS INC
Form 10-Q
August 07, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2014

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-33095

ACHILLION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**52-2113479**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
300 George Street, New Haven, CT	**06511**
(Address of principal executive offices)	**(Zip Code)**

(203) 624-7000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of August 1, 2014, the registrant had 97,788,046 shares of Common Stock, $0.001 par value per share, outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Achillion Pharmaceuticals, Inc.

Balance Sheets

(in thousands, except per share amounts)

(unaudited)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 33,268	$ 33,457
Marketable securities	98,205	88,393
Accounts and other receivables	194	480
Prepaid expenses and other current assets	1,923	2,452
Total current assets	133,590	124,782
Marketable securities		36,139
Fixed assets, net	1,279	1,265
Deferred financing costs	161	79
Restricted cash	152	152
Total assets	$ 135,182	$ 162,417
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 2,004	$ 4,591
Accrued expenses	7,039	4,521
Current portion of long-term debt	164	291
Total current liabilities	9,207	9,403
Long-term debt		56
Total liabilities	9,207	9,459
Commitments and contingencies (Note 12)		
Stockholders Equity:		
Common Stock, $.001 par value; 200,000 shares authorized: 97,787 and 96,792 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	98	97

Additional paid-in capital	539,271	534,529
Accumulated deficit	(413,419)	(381,674)
Accumulated other comprehensive income	25	6
Total stockholders equity	125,975	152,958
Total liabilities and stockholders equity	$ 135,182	$ 162,417

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Statements of Comprehensive Loss

(in thousands, except per share amounts)

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue	$	$	$	$
Operating expenses				
Research and development	12,177	16,568	25,019	25,288
General and administrative	3,589	3,545	6,982	6,619
Total operating expenses	15,766	20,113	32,001	31,907
Loss from operations	(15,766)	(20,113)	(32,001)	(31,907)
Other income (expense)				
Interest income	117	185	275	263
Interest expense	(8)	(12)	(19)	(34)
Net loss	(15,657)	(19,940)	(31,745)	(31,678)
Total comprehensive loss (Note 10)	(15,656)	(20,051)	(31,726)	(31,838)
Basic and diluted net loss per share (Note 4)	$ (0.16)	$ (0.21)	$ (0.33)	$ (0.35)
Weighted average number of shares used in computing basic and diluted net loss per share	97,017	96,580	96,905	91,245

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Statements of Cash Flows

(in thousands)

(unaudited)

	For the Six Months Ended June 30,	
	2014	**2013**
Cash flows from operating activities		
Net loss	$ (31,745)	$ (31,678)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	232	197
Non-cash stock-based compensation	3,197	3,087
Premium on purchases of marketable securities	(724)	(3,077)
Amortization of premium on marketable securities	1,128	956
Changes in operating assets and liabilities:		
Accounts and other receivables	286	(332)
Prepaid expenses and other assets	529	(271)
Accounts payable	(2,587)	2,285
Accrued expenses	2,518	2,422
Net cash used in operating activities	(27,166)	(26,411)
Cash flows from investing activities		
Purchases of fixed assets	(246)	(238)
Purchases of marketable securities	(55,027)	(144,947)
Maturities of marketable securities	80,969	36,865
Net cash provided by (used in) investing activities	25,696	(108,320)
Cash flows from financing activities		
Proceeds from sale of common stock, net of issuance costs		133,211
Proceeds from exercise of stock options	1,450	298
Proceeds from sale of common stock under Employee Stock Purchase Plan	96	105
Payment of deferred financing costs	(82)	
Repayments of debt	(183)	(172)
Net cash provided by financing activities	1,281	133,442
Net increase in cash and cash equivalents	(189)	(1,289)
Cash and cash equivalents, beginning of period	33,457	18,526
Cash and cash equivalents, end of period	$ 33,268	$ 17,237

Supplemental disclosure of cash flow information		
Cash paid for interest	$ 20	$ 27
Supplemental disclosure of non-cash financing activities		
Cashless exercise of warrants	$ 2,848	$

The accompanying notes are an integral part of these financial statements.

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Achillion Pharmaceuticals, Inc.

Notes to Financial Statements

(in thousands, except per share amounts)

(unaudited)

1. Nature of the Business

Achillion Pharmaceuticals, Inc. (the Company) was incorporated on August 17, 1998 in Delaware. The Company is seeking to discover, develop and commercialize innovative drug therapies. The Company is devoting substantially all of its efforts towards product research and development.

The Company incurred losses of $399,557 from inception through June 30, 2014 and had an accumulated deficit of $413,419 at June 30, 2014, which includes preferred stock dividends recognized until the Company s initial public offering in 2006. The Company has funded its operations primarily through the sale of equity securities.

The Company believes that its existing cash, cash equivalents and marketable securities will be sufficient to meet its projected operating requirements through at least June 30, 2015. However, the Company s future capital requirements may change and will depend upon numerous factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of ACH-3422, ACH-3102 and sovaprevir;
- the scope of and costs associated with entering into cooperative study arrangements, CSAs, if any, for the collaborative development of its drug candidates in combination with others drug candidates;
- the costs involved in obtaining regulatory approvals for the Company s drug candidates;
- the scope, prioritization and number of programs the Company pursues;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- the Company s ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact its ability to obtain capital in the future;
- the costs associated with, and the outcome of, lawsuits against the Company, if any;

the Company s acquisition and development of new technologies and drug candidates; and

competing technological and market developments currently unknown to the Company.

In June 2013, the U.S. Food and Drug Administration (the FDA) placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA removed the clinical hold on sovaprevir, allowing the Company to conduct therapeutic trials of sovaprevir in HCV patients with a maximum dose of 200 mg once daily and in single dose studies in healthy volunteers, but the FDA maintained a partial clinical hold on sovaprevir for multiple dose studies that the Company may conduct in healthy volunteers. The Company expects to continue to work collaboratively with the FDA on the continued clinical development of sovaprevir. Following an internal assessment of the Company s protease inhibitor drug candidates, sovaprevir and ACH-2684, the Company has determined to advance sovaprevir in future clinical trials with ACH-3422 and ACH-3102, rather than ACH-2684.

2. Accounting Standards Updates

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers . The objective of ASU 2014-19 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2016 and allows for prospective or retrospective application. The Company does not believe this pronouncement will have a material effect on its financial statements.

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3. Basis of Presentation

The accompanying unaudited financial statements of the Company should be read in conjunction with the audited financial statements and notes as of and for the year ended December 31, 2013 included in the Company s Annual Report on Form 10-K filed with the SEC on March 7, 2014. The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP) for interim financial information, in accordance with the instructions to Form 10-Q and the guidance in Article 10 of Regulation S-X. Accordingly, since they are interim financial statements, the accompanying financial statements do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. The accompanying financial statements reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair statement of the results of operations for the interim periods presented. Interim results are not necessarily indicative of results for a full year.

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the financial statements and notes thereto. A discussion of the Company s critical accounting policies and management estimates is described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in Part I, Item II of this Quarterly Report on Form 10-Q.

4. Earnings (Loss) Per Share (EPS)

Basic EPS is calculated in accordance with ASC 260, *Earnings Per Share*, by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and warrants. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Net loss (numerator)	$ (31,745)	$ (31,678)
Weighted-average shares, in thousands (denominator)	96,905	91,245
Basic and diluted net loss per share	$ (0.33)	$ (0.35)

Potentially dilutive securities outstanding as of June 30, 2014 and 2013 are as follows:

	June 30,	
	2014	2013
	(in thousands)	
Stock options	8,603	7,902
Warrants	4,531	5,348
Total potentially dilutive securities outstanding	13,134	13,250

5. Collaboration Arrangements

GCA Therapeutics, Ltd.

In February 2010, the Company entered into a license agreement (the Agreement) with GCA Therapeutics, Ltd. (GCAT) for elvucitabine, the Company s nucleoside reverse transcriptase inhibitor for the treatment of both hepatitis B virus (HBV) infection and human immunodeficiency virus (HIV) infection. The Agreement was amended and restated in March 2010. The exclusive license grants GCAT the right, through a Chinese joint venture with Tianjing Institute of Pharmaceutical Research, to clinically develop and commercialize elvucitabine in mainland China, Hong Kong and Taiwan.

Under the terms of the Agreement, GCAT, through a sublicense agreement with a Chinese joint venture, T&T Pharma Co., Ltd., will assume all development and regulatory responsibility and associated costs for elvucitabine. The Company did not receive any payment upon the signing of the agreement. Upon the first commercial sale of a licensed product GCAT is obligated to pay $100 to the Company. Further, the Company will be eligible to receive royalties up to 15% of net sales in those territories.

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The Company does not believe that the milestone specified under the Agreement is substantive as achievement of the milestone is based solely on the performance of GCAT and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Agreement, it intends to recognize revenue related to the milestone payment upon achievement of the milestone by GCAT. However, there can be no assurance that GCAT will achieve the milestone or that the Company will receive the related revenue. This Agreement shall be effective, unless earlier terminated, until the expiration of the last to expire royalty term.

Ora, Inc.

In October 2012, the Company entered into a license and development agreement (the Ora Agreement) with Ora, Inc. (Ora) for the worldwide development and commercialization of ACH-702 delivered topically or locally. The Ora Agreement was amended in April 2013. Under the terms of the Ora Agreement, Ora has assumed development and regulatory responsibility and associated costs for ACH-702. Upon initiation of the agreement, the Company received a one-time license fee of $100, which was recognized as revenue upon the completion of the technology transfer by the Company. The Company is eligible to receive up to $4,000 in development milestones and up to $7,000 in commercialization milestones as well as royalties up to 3.5% of net sales. The Company has no further obligations under the Ora Agreement.

The Ora Agreement includes the right to sublicense any or all of the licensed rights, subject to the Company s approval. Ora has agreed to pay the Company 15% of all up-front licensing payments and any other payment allocated to or received by Ora pursuant to any sublicense agreement granted by Ora under the Ora Agreement; provided that such payment is not a royalty on net sales and not a development or commercial milestone already due to Achillion. In December 2012, Ora entered into a sublicense agreement with Taejoon Pharmaceutical Co. for the development of ACH-702.

The Company does not believe that the milestones specified under the Ora Agreement are substantive as achievement of the milestones is based solely on the performance of Ora and its sublicensee(s) and does not relate to any past or future performance by the Company. Because the Company has no performance obligations under the Ora Agreement, it intends to recognize revenue related to any milestone payments upon achievement of the milestone by Ora or its sublicensee(s). The Ora Agreement shall be effective and, unless earlier terminated, will continue until the last sale of each and every licensed product to an unrelated third party by Ora, its affiliate or sublicensee.

6. Marketable Securities

The Company applies the provisions of Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures,* for financial assets and liabilities measured on a recurring basis which requires disclosure that establishes a framework for measuring fair value and expands disclosures in the financial statements. The guidance requires that fair value measurements be classified and disclosed in one of the three categories:

Level 1: Quoted prices in active markets for identical assets and liabilities that the reporting entity has the ability to access at the measurement date;

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; or

Level 3: Unobservable inputs.

The fair value of the Company s marketable securities of $98,205 and $124,532 as of June 30, 2014 and December 31, 2013, respectively, is valued based on level 2 inputs. The Company s investments consist mainly of U.S. government and agency securities, government sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. The Company has assessed these as level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available for sale as defined in ASC 320, *Debt and Equity Securities*. Securities are carried at fair value with the unrealized gains (losses) reported as a separate component of stockholders equity within accumulated other comprehensive income.

The unrealized gain from marketable securities was $25 and $6 at June 30, 2014 and December 31, 2013, respectively.

As of June 30, 2014 and December 31, 2013, none of the Company s investments were determined to be other than temporarily impaired.

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The following table summarizes the Company s investments:

	June 30, 2014				December 31, 2013			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial Paper	$ 8,037	$ 11		$ 8,048	$ 14,190	$ 9		$ 14,199
Corporate Debt Securities	77,166	24	(17)	77,173	95,036	27	(25)	95,038
Government and Agency Securities	12,977	7		12,984	15,300	1	(6)	15,295
Total	$ 98,180	$ 42	(17)	$ 98,205	$ 124,526	$ 37	(31)	$ 124,532

The following table summarizes the contractual maturities of the Company s investments:

	June 30, 2014	December 31, 2013
Mature in less than one year	$ 98,205	$ 88,393
Mature in one to five years		36,139
Total	$ 98,205	$ 124,532

7. Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2014	December 31, 2013
Accrued compensation	$ 1,864	$ 554
Accrued research and development expenses	4,264	3,276
Accrued professional expenses	686	432
Other accrued expenses	225	259
Total	$ 7,039	$ 4,521

Accrued research and development expenses are comprised of amounts owed to third-party contract research organizations, or CROs , clinical investigators, laboratories and data managers for research and development work performed on behalf of the Company.

8. Debt

Debt consists of the following:

	June 30, 2014	December 31, 2013
2011 Credit Facility, payable in monthly installments through March 2015, with interest of 6.44% to 6.79% per annum	$ 164	$ 347
Total debt	164	347
Less: current portion	(164)	(291)
Total long-term debt, net of current portion	$	$ 56

In March 2011, the Company entered into a Master Security Agreement for a $2,000 Capital Expenditure Line of Credit, (the 2011 Credit Facility) with Webster Bank. Under the 2011 Credit Facility, the Company could draw down equipment loan advances for the purchase of new laboratory equipment through March 2013. The purchased equipment serves as collateral for the 2011 Credit Facility. The fair value for this debt would be classified as a level 2 measurement due to the use of inputs based on similar liabilities in the market. At this time, the carrying value approximates fair value.

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9. Stock-Based Compensation

The Company s 2006 Stock Incentive Plan, or the 2006 Plan, is administered by the Company s Board of Directors and provides for the grant of incentive stock options, nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. The Company s officers, employees, consultants, advisors and directors are eligible to receive awards under the 2006 Plan; however, incentive stock options may only be granted to employees. Stock options granted are exercisable for a period determined by the Company, but in no event longer than ten years from the date of the grant. Stock options generally vest ratably over four years. There were 3,430 shares available to be granted under the 2006 Plan as of June 30, 2014.

A summary of the status of the Company s stock option activity for the six months ended June 30, 2014 is presented in the table and narrative below:

	Stock Options	Weighted Average Exercise Price
Outstanding at January 1, 2014	9,083	$ 5.14
Granted	510	3.28
Exercised	(541)	2.68
Forfeited	(326)	3.48
Cancelled	(123)	5.20
Outstanding at June 30, 2014	8,603	$ 5.25
Options exercisable at June 30, 2014	4,520	$ 5.41
Weighted-average fair value of options granted during the period		$ 2.39

The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of the stock-based awards. The assumptions used to value stock options granted are as follows:

	For the Six Months Ended	
	June 30, 2014	June 30, 2013
Expected term of option	5.0 - 6.1 years	5.0 - 6.1 years
Expected volatility	92 - 96%	87 - 88%
Risk free interest rate	1.88 - 2.02%	1.01 - 1.69%
Expected dividend yield	0%	0%

Total compensation expense recorded in the accompanying statements of operations associated with option grants made to employees was $3,160 and $2,978 for the six months ended June 30, 2014 and 2013, respectively. The Company recorded no tax benefit related to these stock options since the Company currently maintains a full valuation allowance on its deferred tax assets.

As of June 30, 2014, the intrinsic value of the stock options outstanding was $23,628, of which $12,650 related to vested stock options and $10,978 related to unvested stock options. The intrinsic value of stock options is calculated based on the difference between the exercise prices of the underlying common stock and the quoted stock price of the Company s common stock as of June 30, 2014.

As of June 30, 2014, the total compensation cost related to unvested stock options not yet recognized in the financial statements is approximately $12,472, net of estimated forfeitures, and the weighted average period over which this amount is expected to be recognized is 1.4 years.

10. Comprehensive Loss

The Company reports and presents comprehensive loss in accordance with ASC 220, *Comprehensive Income*, which establishes standards for reporting and display of comprehensive loss and its components in a full set of general purpose financial statements. The objective of the statement is to report a measure of all changes in equity of an enterprise that result from transactions and other economic events of the period other than transactions with owners (comprehensive loss). The Company s other comprehensive loss arises from net unrealized losses on marketable securities and was immaterial for all periods presented.

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11. Stockholders Equity

Changes in stockholders equity for the six months ended June 30, 2014 and 2013 were as follows:

	For the Six Months Ended June 30,	
	2014	2013
Balance at December 31, 2013 and 2012	$ 152,958	$ 72,047
Net loss	(31,745)	(31,678)
Stock-based compensation	3,197	3,087
Exercise of stock options	1,450	298
Change in unrealized loss on marketable securities	19	(160)
Issuance of common stock		133,211
Issuance of common stock under the Employee Stock Purchase Plan	96	105
Balance at June 30, 2014 and 2013	$ 125,975	$ 176,910

12. Commitments and Contingencies

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations.

On May 5, 2014, the lead plaintiffs in the previously disclosed consolidated class action lawsuit originally filed in October 2013 against the Company and certain of its current and former officers in the United States District Court for the District of Connecticut voluntarily dismissed all of their claims without prejudice. The Court approved the voluntary dismissal and closed the case on May 6, 2014. A dismissal without prejudice does not prevent the litigation of the same claims in a subsequent action.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. All statements other than statements relating to historical matters including statements to the effect that we believe, expect, anticipate, plan, target, intend and similar expressions should be considered forward-looking statements. Our actual results could differ materially from those discussed in the forward-looking statements as a result of a number of important factors, including factors discussed in this section and elsewhere in this Quarterly Report on Form 10-Q, including those discussed in Item 1A of this report under the heading Risk Factors, and the risks discussed in our other filings with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management s analysis, judgment, belief or expectation only as the date hereof. We assume no obligation to update these forward-looking statements to reflect events or circumstances that arise after the date hereof except as required by law.

Overview

We are a biopharmaceutical company that is seeking to discover, develop and commercialize innovative treatments for infectious diseases. We are currently focusing our efforts on developing commercially competitive, short-duration combination therapies for the treatment of chronic hepatitis C virus, or HCV, infection that are once-daily and ribavirin-free. Specifically, we are advancing:

ACH-3422, a NS5B nucleotide polymerase inhibitor, currently in phase I clinical development;

ACH-3102, a NS5A inhibitor, currently in phase II clinical development; and

Sovaprevir, a NS3/4A protease inhibitor, currently in phase II clinical development.

In June 2013, the U.S. Food and Drug Administration, or FDA, placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA removed the clinical hold on sovaprevir, allowing us to conduct therapeutic trials of sovaprevir in HCV patients with a maximum dose of 200 mg once daily and in single dose trials in healthy volunteers, but the FDA maintained a partial clinical hold on sovaprevir for multiple dose studies that we may conduct in healthy volunteers. Following an internal assessment of our protease inhibitor drug candidates, sovaprevir and ACH-2684, we have determined to advance sovaprevir in future clinical trials with ACH-3422 and ACH-3102, rather than ACH-2684.

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In addition to our work in anti-infectives, we are leveraging our expertise in structure-based drug design to develop small molecule therapeutics with well-characterized biologic activity. In particular, we are working to identify novel small molecule compounds that can be administered orally for the treatment of immune system-related rare diseases. We plan to nominate our first lead small molecule compound in this immunology program later this year.

We have also established a pipeline of certain antibacterial product candidates for which we have sought appropriate collaborative partners, and to which we are not currently devoting significant resources. We have also developed and out licensed certain development and commercialization rights to elvucitabine, for the treatment of both hepatitis B virus, or HBV, and human immunodeficiency virus, or HIV.

We have devoted and are continuing to devote substantially all of our efforts toward product research and development. We have incurred losses of $399.6 million from inception through June 30, 2014 and had an accumulated deficit of $413.4 million at June 30, 2014, which includes preferred stock dividends recognized until our initial public offering in 2006. Our net losses were $31.7 million and $31.7 million for the six months ended June 30, 2014 and 2013, respectively.

We have funded our operations primarily through proceeds from the sale of equity securities. Through June 30, 2014, we have received approximately $515.9 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering, private placements of our common stock and registered offerings of our common stock.

We expect to incur substantial and increasing losses for at least the next several years as we seek to:

- continue clinical development of ACH-3422, ACH-3102 and sovaprevir; and
- identify and progress additional drug candidates.

We will need substantial additional financing to obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities, which we will seek to raise through public or private equity or debt financings, collaborative or other arrangements with third parties or through other sources of financing. There can be no assurance that such funds will be available on terms favorable to us, if at all.

In addition to the risks associated with being an early-stage drug development company, there can be no assurance that we will successfully advance or complete our research and development programs, obtain adequate patent protection for our technology, obtain necessary government regulatory approval for drug candidates we develop, find and maintain appropriate collaboration partners or that any approved drug candidates will be commercially viable. In addition, we may not be profitable even if we succeed in commercializing any of our drug candidates.

Financial Operations Overview

Revenue

During the three and six months ended June 30, 2014 and 2013 we did not recognize any revenue.

Research and Development

Our research and development expenses reflect costs incurred for our proprietary research and development projects which consist primarily of salaries and benefits for our research and development personnel, costs of services by clinical research organizations, other outsourced research, materials used during research and development activities, facility-related costs such as rent and utilities associated with our laboratory and clinical development space and operating supplies.

Within the anti-infectives market, we are concentrating on the development of antivirals for the treatment of HCV. Currently, we are focused on developing combination regimens using our drug candidates for the treatment of HCV, including ACH-3422 plus ACH-3102, both with and without sovaprevir. In the near term, we intend to focus our efforts on (i) continuing a phase I/Ib clinical trial of ACH-3422, (ii) continuing an eight and six week clinical trial with ACH-3102 and sofosbuvir, a marketed nucleotide polymerase inhibitor that we believe is a proxy for future use of our nucleotide polymerase inhibitor, ACH-3422, since sofosbuvir is in the same class of drugs as ACH-3422, (iii) initiating a multiple dose drug-drug interaction study with sovaprevir plus compounds that potentially impact active transport mechanisms in the liver and intestines, and (iv) exploring potential development of our drug candidates with other drug developers under cooperative or other study arrangements.

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In addition to our work in anti-infectives, we are leveraging our expertise in structure-based drug design to develop small molecule therapeutics with well-characterized biologic activity. In particular, we are working to identify novel small molecule compounds that can be administered orally for the treatment of immune system related rare diseases. We plan to nominate our first lead small molecule compound in this immunology program later this year.

We have established our current HCV drug candidate pipeline entirely through our internal discovery capabilities. Through these efforts, we have identified the following portfolio of drug candidates which we intend to study in combination with each other and/or potentially in combination with compounds owned by others:

ACH-3422, a NS5B Nucleotide Polymerase Inhibitor. We are developing combination regimens to address all HCV genotypes based on use of ACH-3422, our nucleotide prodrug inhibitor of HCV NS5B polymerase, in combination with ACH-3102, our NS5A inhibitor, and potentially with a NS3/4A protease inhibitor. In vitro, ACH-3422 has demonstrated excellent potency, with activity demonstrated across all genotypes of HCV and an EC50, or concentration effective enough to eliminate 50% of the virus, of approximately 50 to 65 nanomolar against genotype 1 HCV. We have completed a 28-day safety study in animals in which no significant findings were noted. ACH-3422 appears to have high oral bioavailability, rapid uptake and conversion of the prodrug into the monophosphate within the liver, and a pharmacokinetic profile supportive of once-daily dosing. In April, we initiated a phase I/Ib first-in-human clinical trial of ACH-3422 outside the United States. We expect data from this trial to be available in Fall 2014. We plan to initiate a clinical trial based on ACH-3422 in combination with other of our direct acting anti-virals, or DAAs, pending regulatory approval, by the end of 2014.

ACH-3102, a NS5A Inhibitor. We are developing combination drug regimens that also include ACH-3102, our pan-genotypic, second generation NS5A inhibitor. To date, we have completed two phase II 12-week clinical trials with ACH-3102 including the -007 trial with sovaprevir described below, which examined the use of ACH-3102 in combination with sovaprevir and ribavirin, and the -005 study, which examined the use of ACH-3102 with ribavirin alone. Results from these studies indicate that ACH-3102 is uniquely potent against HCV genotype 1b and was well tolerated with no drug-related serious adverse events. All patients in the -007 trial achieved a very rapid virologic response, or vRVR, meaning undetectable levels of HCV RNA (less than 25 IU (international units)/ml) by week 2 of treatment. Also in the -007 study, all patients infected with HCV genotype 1b achieved SVR24, meaning undetectable levels of HCV RNA twenty-four weeks after cessation of dosing. In the -005 study, ACH-3102 in combination with ribavirin demonstrated potent anti-HCV activity even in the presence of multiple drug resistant mutations observed at baseline, and while vRVR was achieved by the majority of patients, SVR12 was not achieved in the majority of patients. To date, we have not been able to generate any resistant mutations to ACH-3102 in genotype 1b HCV. ACH-3102 has been granted Fast Track status by the FDA.

Sovaprevir, **a NS3/4A Protease Inhibitor.** We recently completed a randomized, double-blind phase II clinical trial that evaluated 12 weeks of treatment consisting of sovaprevir and our NS5A inhibitor, ACH-3102, with ribavirin for the treatment of genotype 1 HCV (the -007 trial). For further discussions of this trial please see ACH-3102, a NS5A Inhibitor, above. In June 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA lifted the full clinical hold, allowing us to advance sovaprevir in clinical trials of

HCV-infected patients, but requiring us to seek FDA approval to conduct multi-dose clinical trials in healthy subjects. Following an internal assessment of our protease inhibitor drug candidates, sovaprevir and ACH-2684, we determined to advance sovaprevir in future clinical trials with ACH-3422 and ACH-3102, rather than ACH-2684. We plan to initiate a drug-drug interaction study with sovaprevir plus compounds that potentially impact active transport mechanisms in the liver and intestines in the fourth quarter of 2014.

ACH-2684, a NS3/4A Protease Inhibitor. We most recently completed phase Ib proof-of-concept clinical studies of ACH-2684, including three segments: once-daily dosing in genotype 1, twice-daily dosing in patients with genotype 3, and once-daily dosing in patients with cirrhosis. Cirrhosis is an abnormal liver condition characterized by irreversible scarring of the liver. Once-daily doses of 400mg of ACH-2684 reduced viral load by a mean maximum 3.73 $\log_{10}$ in genotype 1 HCV patients. In addition, twice daily doses of 400mg of ACH-2684 reduced viral load by a maximal 2.03 $\log_{10}$ in patients with HCV genotype 3. Lastly, once-daily doses of 400mg administered for three days to HCV patients with cirrhosis reduced viral load by a mean maximum 3.67 $\log_{10}$ reduction, similar to the antiviral activity achieved in non-cirrhotic genotype 1 HCV patients receiving the same dose of ACH-2684. ACH-2684 demonstrated good safety and tolerability in these phase Ib clinical studies, as well as in phase Ia studies in healthy volunteers. Following an internal assessment of our protease inhibitor drug candidates, sovaprevir and ACH-2684, we determined to advance sovaprevir in future clinical trials with ACH-3422 and ACH-3102, rather than ACH-2684.

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We intend to continue to focus on the discovery and development of new drug candidates through our extensive expertise in biology and medicinal chemistry. Although significant additional funding and research and development will be required to support these efforts, we believe our drug discovery capabilities will allow us to further expand our product candidate portfolio, providing us with strong growth potential.

All costs associated with internal research and development, and research and development services for which we have externally contracted, are expensed as incurred. The costs of obtaining patents for our candidates are expensed as incurred as indirect costs.

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	
Clinical candidate direct external costs:		
ACH-3422 (and related compounds)	$ 6,298	$ 223
ACH-3102 (and related compounds)	2,322	4,861
Sovaprevir (and related compounds)	875	4,503
ACH-2684 (and related compounds)	1,315	629
Sovaprevir/ACH-3102 combination trials	685	7,423
ACH-3102/ACH-2684 combination trial	2,001	7
ACH-3102/sofosbuvir combination trial	1,578	
Other	882	275
	15,956	17,921
Direct internal personnel costs	6,781	5,620
Sub-total direct costs	22,737	23,541
Indirect costs and overhead	2,432	1,837
Research and development tax credit	(150)	(90)
Total research and development	$ 25,019	$ 25,288

The State of Connecticut provides companies with the opportunity to exchange certain research and development credit carryforwards for cash in exchange for foregoing the carryforward of the research and development credit. The program provides for such exchange of the research and development credit at a rate of 65% of the annual research and development credit, as defined. The benefit for such exchange is recorded as a reduction of research and development expenditures.

We expect research and development expenses associated with the completion of these programs to be substantial and to increase over time. However, we do not believe that it is possible at this time to know or accurately project the nature, timing or total amount of program-specific expenses through commercialization. There exist numerous factors associated with the successful commercialization of any of our drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will evolve and therefore impact our clinical development programs and plans over time.

General and Administrative

Our general and administrative expenses consist primarily of salaries and benefits for management and administrative personnel, professional fees for legal, accounting and other services, travel costs and facility-related costs such as rent, utilities and other general office expenses for general and administrative personnel.

Critical Accounting Standards and Estimates

Preparation of our financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. A summary of our critical accounting estimates is included in Management s Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2013. We continually review these estimates and their underlying assumptions to ensure they are appropriate for the circumstances. Changes in the estimates and assumptions we use could have a significant impact on our financial results. During the first six months of 2014, there were no significant changes in our estimates and critical accounting policies.

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Results of Operations

Results of operations may vary from period to period depending on numerous factors, including the timing of payments received under existing or future strategic alliances, joint ventures or financings, if any, the progress of our research and development projects, technological advances and determinations as to the commercial potential of proposed products.

Comparison of Three and Six Months Ended June 30, 2014 and 2013

Research and Development Expenses. Research and development expenses were $12.2 million and $16.6 million for the three months ended June 30, 2014 and 2013, respectively, and $25.0 million and $25.3 million for the six months ended June 30, 2014 and 2013, respectively. The decrease for the three and six months ended June 30, 2014 was primarily due to decreased clinical trial and manufacturing costs related to combination clinical trials of sovaprevir and ACH-3102, partially offset by increased preclinical, manufacturing and clinical costs related to ACH-3422 and ACH-3102 combination trials with ACH-2684 and sofosbuvir, as well as increased outsourced research and consulting fees. Additionally, manufacturing costs related to ACH-2684 increased. Personnel costs and non-cash stock-based compensation also increased primarily due to the addition of personnel in our development group. We expect research and development expenses during the remainder of the year to be consistent with the first half of the year. Research and development expenses for the three and six months ended June 30, 2014 and 2013 are comprised as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014	2013	Change	% Change	2014	2013	Change	% Change
Personnel costs	$ 2,819	$ 2,300	$ 519	23%	$ 5,537	$ 4,580	$ 957	21%
Stock-based compensation	645	481	164	34%	1,244	1,040	204	20%
Outsourced research and supplies	7,002	12,488	(5,486)	(44)%	14,641	17,148	(2,507)	(15)%
Professional and consulting fees	1,134	707	427	60%	2,443	1,410	1,033	73%
Facilities costs	532	484	48	10%	1,040	1,002	38	4%
Travel and other costs	127	153	(26)	(17)%	264	198	66	33%
Research and development tax credit	(82)	(45)	(37)	82%	(150)	(90)	(60)	(67)%
Total	$ 12,177	$ 16,568	$ (4,391)	(27)%	$ 25,019	$ 25,288	(269)	(1)%

General and Administrative Expenses. General and administrative expenses were $3.6 million and $3.5 million for the three months ended June 30, 2014 and 2013, respectively, and $7.0 million and $6.6 million for the six months ended June 30, 2014 and 2013, respectively. The increase for the three months ended June 30, 2014 was primarily due to increased corporate legal and insurance fees, partially offset by decreased non cash stock compensation and consulting fees. The increase for the six months ended June 30, 2014 was primarily due to increased corporate legal fees, offset by decreased consulting fees. We expect general and administrative expenses during the remainder of the year to be consistent with the first half of the year. General and administrative expenses for the three and six months ended June 30, 2014 and 2013 are comprised as follows:

	Three Months Ended June 30,				Six Months Ended June 30,			
	2014	2013	Change	% Change	2014	2013	Change	% Change
Personnel costs	$ 983	$ 908	$ 75	8%	$ 1,960	$ 1,808	$ 152	8%
Stock-based compensation	996	1,183	(187)	(16)%	1,953	2,047	(94)	(5)%
Professional and consulting fees	1,075	962	113	12%	2,028	1,830	198	11%
Facilities costs	222	162	60	37%	392	324	68	21%
Travel and other costs	313	330	(17)	(5)%	649	610	39	6%
Total	$ 3,589	$ 3,545	$ 44	1%	$ 6,982	$ 6,619	$ 363	5%

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Other Income (Expense). Interest income was $117,000 and $185,000 for the three months ended June 30, 2014 and 2013, respectively. The $68,000, or 37%, decrease was primarily due to decreased average cash balances in 2014. Interest expense was $8,000 and $12,000 for the three months ended June 30, 2014 and 2013, respectively.

Interest income was $275,000 and $263,000 for the six months ended June 30, 2014 and 2013, respectively. Interest expense was $19,000 and $34,000 for the six months ended June 30, 2014 and 2013, respectively. The $15,000, or 44%, decrease was primarily due to lower average debt facility balances outstanding in 2014.

Liquidity and Capital Resources

Since our inception in August 1998, we have financed our operations primarily through proceeds from the sale of equity securities. Through June 30, 2014, we have received approximately $515.9 million in aggregate gross proceeds from stock issuances, including convertible preferred stock, our initial public offering, private placements of our common stock and registered offerings of our common stock, including the following:

- In February 2013, we issued 16,894,410 shares of our common stock in an underwritten public offering, including the underwriter s exercise of an over-allotment option. We received net proceeds of $133.2 million;
- In August 2012, we issued 6,367,853 shares of our common stock in a registered direct offering with funds managed by QVT Financial LP. We received net proceeds of $41.7 million;
- In June 2011, we issued 11,040,000 shares of our common stock in an underwritten public offering, including the underwriters exercise of an over-allotment option. We received net proceeds of $60.9 million;
- In August 2010, we issued 19,775,101 shares of our common stock and warrants to purchase 6,921,286 shares of common stock in a private placement to institutional and other accredited investors. We received net proceeds of $49.9 million; and
- In January 2010, we issued 10,275,000 shares of our common stock in an underwritten public offering. In February 2010, we issued an additional 1,541,250 shares of common stock in connection with the underwriters exercise of an over-allotment option. We received net proceeds of $22.6 million.

As of June 30, 2014, our debt balance due to borrowings was $164,000 with an interest rate of 6.44%.

We had $131.0 million and $158.0 million in cash, cash equivalents and marketable securities as of June 30, 2014 and December 31, 2013, respectively. We regularly review our investments and monitor the financial markets. As of June 30, 2014, our cash, cash equivalents and marketable securities included high-quality financial instruments, primarily money market funds, government sponsored bond obligations and other corporate debt securities which we believe are subject to limited credit risk.

Cash used in operating activities was $27.2 million for the six months ended June 30, 2014 and was primarily attributable to our $31.7 million net loss combined with a $2.6 million decrease in accounts payable, partially offset by $3.2 million in non-cash stock-based compensation and a $2.5 million increase in accrued expenses. Cash used in

operating activities was $26.4 million for the six months ended June 30, 2013 and was primarily attributable to our $31.7 million net loss combined with $3.1 million in premiums paid on the purchase of marketable securities, partially offset by non-cash stock-based compensation and increases in accounts payable and accrued expenses.

Cash provided by investing activities was $25.7 million for the six months ended June 30, 2014 and was primarily attributable to $81.0 million in maturities of marketable securities, partially offset by $55.0 million in purchases of marketable securities. Cash used in investing activities was $108.3 million for the six months ended June 30, 2013 and was primarily attributable to $144.9 million in purchases of marketable securities, partially offset by maturities of marketable securities.

Cash provided by financing activities was $1.3 million for the six months ended June 30, 2014 and was primarily attributable to $1.5 million in proceeds from the exercise of stock options, partially offset by repayments of debt. Cash provided by financing activities was $133.4 million for the six months ended June 30, 2013 and was primarily attributable to $133.2 million in net proceeds from our public offering in February 2013.

We expect to incur continuing and increasing losses from operations for at least the next several years as we seek to:

- continue clinical development of ACH-3422, ACH-3102, and sovaprevir; and
- identify and progress additional drug candidates.

We do not expect our existing capital resources, together with any milestone payments and research and development funding we may receive, to be sufficient to fund the completion of the development of any of our drug candidates. As a result, we will need to raise additional funds prior to, among other things, being able to market any drug candidates, to obtain regulatory approvals, fund

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operating losses, and, if deemed appropriate, establish manufacturing and sales and marketing capabilities. We will seek to raise such additional financing through (i) public or private equity or debt financings, (ii) collaborative or other arrangements with third parties or (iii) other sources of financing.

We believe that our existing cash, cash equivalents, and marketable securities will be sufficient to meet our projected operating requirements through at least June 30, 2015. However, our future capital requirements may change and will depend upon numerous factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of ACH-3422, ACH-3102, and sovaprevir;
- the scope of and costs associated with entering into cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates in combination with third-party drug candidates;
- the costs involved in obtaining regulatory approvals for our drug candidates;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- our ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact our ability to obtain capital in the future;
- the costs associated with, and the outcome of, lawsuits against us, if any;
- our acquisition and development of new technologies and drug candidates; and
- competing technological and market developments currently unknown to us.

We intend to augment our cash balance through financing transactions, including the issuance of debt or equity securities, and/or further corporate alliances. There can be no assurance that we will be able to obtain adequate levels of additional funding on favorable terms, if at all. If adequate funds are not available, we will be required to:

- delay, reduce the scope of or eliminate research and development programs;

obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently; and/or

pursue merger or acquisition strategies.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates. We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect stockholders rights.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers . The objective of ASU 2014-19 is to establish a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most of the existing revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard is effective for annual reporting periods beginning after December 15, 2016 and allows for prospective or retrospective application. We do not believe this pronouncement will have a material effect on our financial statements.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk. Our exposure to market risk is confined to our cash, cash equivalents and marketable securities. We regularly review our investments and monitor the financial markets. We invest in high-quality financial instruments, primarily money market funds, government sponsored bond obligations and government-backed corporate debt securities, with the effective duration of the portfolio less than twelve months and no security with an effective duration in excess of twenty four months, which we believe are subject to limited credit risk. We currently do not hedge interest rate exposure. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We do not believe that we have any material exposure to interest rate risk or changes in credit ratings arising from our investments.

Capital Market Risk. We currently have no product revenues and depend on funds raised through other sources. One source of funding is through future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2014, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective, at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a 15(d) and 15d 15(d) under the Exchange Act) occurred during the fiscal quarter ended June 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Class Actions

On May 5, 2014, without any settlement payment by us, any individual defendant or any third party on their behalf, the lead plaintiffs in the previously disclosed consolidated class action lawsuit originally filed in October 2013 against us and certain of our current and former officers in the United States District Court for the District of Connecticut

voluntarily dismissed all of their claims without prejudice. The Court approved the voluntary dismissal and closed the case on May 6, 2014. A dismissal without prejudice does not prevent the litigation of the same claims in a subsequent action.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations. These risk factors restate and supersede in their entirety the risk factors previously disclosed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013.

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Risks Related to Our Business

We depend on the success of our HCV drug candidates, which are still under development.

We have invested a significant portion of our efforts and financial resources in the development of our candidates for the treatment of HCV, including our nucleotide polymerase inhibitor, ACH-3422, our NS5A inhibitor, ACH-3102, and our protease inhibitor, sovaprevir. Our ability to generate revenues will depend heavily on the successful development and commercialization of these drug candidates. The development and commercial success of these drug candidates will depend on several factors, including the following:

- our ability to provide acceptable evidence of the safety and efficacy of these drug candidates in current and future clinical trials;
- our ability to provide acceptable evidence of the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;
- our ability to develop drug formulations that will deliver the appropriate drug exposures in longer term clinical trials;
- our ability to obtain patent protection for our drug candidates and freedom to operate under third-party intellectual property;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;
- establishing commercial manufacturing arrangements with third-party manufacturers;
- launching commercial sales of successfully developed drugs, whether alone or in collaboration with others, particularly in a market in which competing therapeutics have very high efficacy rates;
- acceptance of drugs in the medical community and with third-party payors; and
- our ability to identify, enter into and maintain collaboration arrangements with appropriate strategic partners for our drug candidates.

Positive results in preclinical studies of a drug candidate may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of a drug candidate may not be replicated in later clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the preclinical studies or completed clinical trials for ACH-3422, ACH-3102, or sovaprevir may not be

predictive of the results we may obtain in later stage trials.

We do not expect any of our drug candidates for the treatment of HCV to be commercially available for at least several years, if at all.

As a result of elevations in liver enzymes noted in a phase I drug-drug interaction study for healthy volunteers evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir, the FDA previously placed a clinical hold on sovaprevir. While the FDA removed its clinical hold on sovaprevir for single dose studies in June 2014, the FDA maintained a partial clinical hold on sovaprevir for certain multiple dose studies in healthy volunteers. Our business may be adversely affected if such regulatory concerns lead to delays in developing sovaprevir or if elevated liver enzyme levels or other adverse drug-drug interactions are observed in subsequent studies.

One of our most advanced compounds under development is sovaprevir, a NS3/4A protease inhibitor in phase II clinical development. In June 2013, the FDA placed a clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subjects drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. In June 2014, the FDA removed the clinical hold on sovaprevir, allowing us to conduct therapeutic trials of sovaprevir in HCV patients with a maximum dose of 200 mg once daily and in single dose studies in healthy volunteers, but the FDA maintained a partial clinical hold on sovaprevir for multiple dose studies that we may conduct in healthy volunteers.

The FDA may not remove the partial clinical hold on sovaprevir and may not allow us to conduct additional multiple dose studies in healthy volunteers without their prior permission. Moreover, elevated liver enzymes or other adverse drug-drug interactions could be observed in our ongoing phase II clinical trial or any other subsequent preclinical studies or clinical trials that we may conduct. If the FDA does not remove the partial clinical hold or if elevated liver enzymes or other adverse drug-drug interactions are observed, our development of sovaprevir may be delayed, and the associated costs may be significantly increased, adversely affecting our business. If the FDA places sovaprevir on clinical hold again, we may terminate the development of sovaprevir, which may adversely affect our business.

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Our market is subject to intense competition. If we are unable to compete effectively, our drug candidates may be rendered noncompetitive or obsolete.

We are engaged in a segment of the pharmaceutical industry that is highly competitive and rapidly changing. We face potential competition from many different sources pursuing the development of novel drugs that target infectious diseases generally and HCV in particular, including both major and specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research organizations. We face, and expect to continue to face, intense and increasing competition as new products enter the market and advanced technologies become available. In addition to currently approved drugs, there are a significant number of drugs that are currently under development and may become available in the future for the treatment of HCV. Additionally, there may be competitive drugs currently under development of which we are not aware.

If approved, our drug candidates that we are advancing, ACH-3422, ACH-3102, and sovaprevir, would compete with drugs currently approved for the treatment of HCV, i.e., the interferon-alpha-based products from Roche (Pegasys and Roferon-A) or Merck (Intron-A or Peg-Intron), the ribavirin-based products from Merck (Rebetrol), Roche (Copegus) and generic versions sold by various companies, as well as recently-approved protease inhibitors telaprevir by Vertex (Incivek®), boceprevir by Merck (Victrelis®) and simeprevir by Johnson and Johnson (Olysio) and recently approved nucleotide inhibitor sofosbuvir by Gilead Sciences (Sovaldi .)

If approved, our drug candidates may also compete with all-oral treatments currently in development to treat HCV infection in multiple classes including protease inhibitors, polymerase inhibitors (nucleoside, nucleotide, and non-nucleoside), NS5A inhibitors and cyclophilin inhibitors. Competing drug candidates for the treatment of HCV, or combinations of drug candidates, are being developed by companies such as AbbVie, Astra-Zeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Johnson & Johnson, Presidio, Medivir, Merck, Novartis, Pfizer, Roche, Valeant and Vertex.

Many of our competitors have:

- significantly greater financial, technical and human resources than we have and may be better equipped to discover, develop, manufacture and commercialize drug candidates;
- more extensive experience in preclinical testing and clinical trials, obtaining regulatory approvals and manufacturing and marketing pharmaceutical products;
- drug candidates that have been approved or are in late-stage clinical development; and/or
- collaborative arrangements in our target markets with leading companies and research institutions.

Mergers and acquisitions in the pharmaceutical and biotechnology industry may result in even more resources being concentrated among a smaller number of our competitors. For example, in August 2014, Merck completed its acquisition of Idenix Pharmaceuticals, Inc., a potential competitor of ours. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Competitive products, specific classes of competitive products, or combinations of competitive products, may render our products obsolete or noncompetitive before we can recover the expenses of developing and commercializing our drug candidates. Furthermore, the development of new treatment methods for the diseases we are targeting could render our drug candidates noncompetitive, obsolete or uneconomical. If we successfully develop and obtain approval for any of our drug candidates, we will face competition based on the safety and effectiveness of our drug candidates, the timing of their entry into the market in relation to competitive products in development, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. If we successfully develop drug candidates but those drug candidates do not achieve and maintain market acceptance, our business will not be successful.

We have a limited operating history and have incurred a cumulative loss since inception. If we do not generate significant revenues, we will not be profitable.

We have incurred significant losses since our inception in August 1998. As of June 30, 2014, our accumulated deficit was approximately $413 million. We have not generated any revenue from the sale of drug candidates to date. We expect that our annual operating losses will increase over the next several years as we expand our research, development and commercialization efforts.

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To become profitable, we must successfully develop and obtain regulatory approval for our drug candidates and effectively manufacture, market and sell any drug candidates we develop. Accordingly, we may never generate significant revenues and, even if we do generate significant revenues, we may never achieve profitability.

We will need substantial additional capital to fund our operations, including drug candidate development, manufacturing and commercialization. If we do not have or cannot raise additional capital when needed, we will be unable to develop and commercialize our drug candidates successfully, and our ability to operate as a going concern may be adversely affected.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our current projected operating requirements through at least June 30, 2015. However, our future capital requirements may change and will depend upon numerous factors, including but not limited to:

- the costs involved in the clinical development, manufacturing and formulation of ACH-3422, ACH-3102, and sovaprevir;
- the scope of and costs associated with entering into cooperative study arrangements, or CSAs, if any, for the collaborative development of our drug candidates in combination with others drug candidates;
- the costs involved in obtaining regulatory approvals for our drug candidates;
- the scope, prioritization and number of programs we pursue;
- the costs involved in preparing, filing, prosecuting, maintaining, enforcing and defending patent and other intellectual property claims;
- our ability to raise incremental debt or equity capital, including any changes in the credit or equity markets that may impact our ability to obtain capital in the future;
- the costs associated with, and the outcome of, lawsuits against us, if any;
- our acquisition and development of new technologies and drug candidates; and
- competing technological, regulatory and market developments currently unknown to us.

We intend to augment our cash balance through financing transactions, including through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. For example, in November 2012 we entered into an agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which, from time to time, we may offer and sell up to $50,000,000 of shares of our common stock at the market

through Cantor pursuant to an effective universal shelf registration statement. If we issue additional securities pursuant to this shelf registration statement, these securities would be available for immediate resale in the public market.

Since August 2008, we have issued an aggregate of 76,608,269 shares of our common stock in two private placements and four registered offerings as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of June 30, 2014, we have 4,530,969 warrants outstanding at a weighted average exercise price of $3.12. These financings substantially diluted our existing stockholders.

There can be no assurance that we will be able to obtain adequate levels of additional funding on favorable terms, if at all. If adequate funds are not available, we will be required to:

- delay, reduce the scope of or eliminate research and development programs;
- obtain funds through arrangements with collaborators or others on terms unfavorable to us or that may require us to relinquish rights to certain drug candidates that we might otherwise seek to develop or commercialize independently; and/or
- pursue merger or acquisition strategies.

If our operating plan changes, we may need additional funds sooner than planned. Such additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay preclinical studies, clinical trials or other development activities for one or more of our drug candidates. We may seek additional financing through a combination of private and public equity offerings, debt financings and collaboration, strategic alliance and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest will be diluted, and the terms may include adverse liquidation or other preferences that adversely affect stockholders rights.

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If we acquire or license technologies, resources or drug candidates, we will incur a variety of costs and may never realize benefits from the transaction.

If appropriate opportunities become available, we may license or acquire technologies, resources, drugs or drug candidates. We may never realize the anticipated benefits of such a transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the drug candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, material impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

If we are not able to attract and retain key management, scientific personnel and advisors, we may not successfully develop our drug candidates or achieve our other business objectives.

We depend upon our senior management and scientific staff for our business success. All of our employment agreements with our senior management employees are terminable without notice by the employee. The loss of the service of any of the key members of our senior management may significantly delay or prevent the achievement of drug development and other business objectives. Our ability to attract and retain qualified personnel, consultants and advisors is critical to our success. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. We may be unable to attract and retain these individuals, and our failure to do so would adversely affect our business.

If biopharmaceutical companies involved in HCV drug development continue to consolidate, competition in our industry may increase and our business may be harmed.

In recent years, several acquisitions of smaller biopharmaceutical companies by larger biopharmaceutical companies took place at substantial premiums over the market capitalizations of the target companies, including the acquisitions of Anadys Pharmaceuticals, Pharmasset, Inc. and Inhibitex Pharmaceuticals, by Roche, Gilead and Bristol-Myers Squibb, respectively. Most recently, in August 2014, Merck completed their planned acquisition of Idenix Pharmaceuticals, Inc. As such consolidation continues to take place, we may face competitive pressures to a far greater degree than had those consolidations not occurred, resulting from the greater resources the larger biopharmaceutical companies can put toward their development pipelines. Further, if investors who provide capital to our industry continue to seek and advocate for similar acquisitions at similar premiums, we may not be able to satisfy their higher expectations for market value appreciation and our stock price may decline. In addition, such acquisitions at significant premiums to market price tend to increase volatility of stock prices in our industry, potentially making investors wary of making incremental investment in us.

Our business has a substantial risk of product liability claims. If we are unable to obtain or maintain appropriate levels of insurance, a product liability claim could adversely affect our business.

Our business exposes us to significant potential product liability risks that are inherent in the development, manufacturing and sales and marketing of human therapeutic products. Although we do not currently commercialize any products, claims could be made against us based on the use of our drug candidates in clinical trials. Product liability claims could delay or prevent completion of our clinical development programs. We currently have clinical trial insurance in an amount equal to up to $20.0 million in the aggregate and will seek to obtain product liability insurance prior to the sales and marketing of any of our drug candidates. However, our insurance may not provide adequate coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to maintain current amounts of insurance coverage or obtain additional or sufficient insurance at a reasonable cost to protect against losses that could have a material adverse effect

on us. If a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a successful claim. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct significant financial and managerial resources to such defense, and adverse publicity is likely to result.

If the estimates we make and the assumptions on which we rely in preparing our financial statements prove inaccurate, our actual results may vary significantly.

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses. Such estimates and judgments include revenue recognition, stock-based compensation expense, accrued expenses and deferred tax assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. However, these estimates and judgments, or the assumptions underlying them, may change over time. Accordingly, our actual financial results may vary significantly from the estimates contained in our financial statements.

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For a further discussion of the estimates and judgments that we make and the critical accounting policies that affect these estimates and judgments, see Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Standards and Estimates elsewhere in this Quarterly Report on Form 10-Q.

Our business and operations would suffer in the event of system failures or security breaches.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liabilities and the further development of our product candidates may be delayed.

Risks Related to the Development of Our Drug Candidates

All of our drug candidates are still in the early stages of development and remain subject to clinical testing and regulatory approval. If we are unable to successfully develop, test and commercialize our drug candidates, we will not be successful.

To date, we have not commercially marketed, distributed or sold any drug candidates. The success of our business depends primarily upon our ability to develop and commercialize our drug candidates successfully. Our drug candidates must satisfy rigorous standards of safety and efficacy before they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy testing and obtain regulatory approval of our drug candidates. Despite our efforts, our drug candidates may not:

- offer therapeutic or other improvement over existing, comparable drugs;
- be proven safe and effective in clinical trials;
- have the desired effects, or may include undesirable effects or may have other unexpected characteristics;
- meet applicable regulatory standards;
- be capable of being produced in commercial quantities at acceptable costs; or
- be successfully commercialized.

In addition, we may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including:

regulators or Institutional Review Boards, or IRBs, may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

our preclinical tests or clinical trials for our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials, or we may abandon projects that we expect to be promising;

we might have to suspend or terminate our clinical trials if the participants in our trials, or in third-party trials of similar HCV drug candidates, are exposed to unacceptable health risks;

IRBs or regulators, including the FDA, may require that we hold, suspend or terminate clinical research for various reasons, such as the FDA s recent decision to place a clinical hold on sovaprevir, or noncompliance with regulatory requirements;

due to the high SVR rates demonstrated by newly approved, competitive therapies like nucleotide polymerase inhibitor sofosbuvir (Sovaldi), the FDA may require us to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies and analysis, resulting in significant delays and/or increased costs;

enrollment in our clinical trials may be slower than we currently anticipate as potential participants have access to commercially launched DAAs, telaprevir (Incivek®), boceprevir (Victrelis®), simeprevir (Olysio) or sofosbuvir (Sovaldi), as well as other experimental therapies under development, or participants may not remain adherent to our clinical trial protocols or may drop out of our clinical trials at a higher rate than we currently anticipate, each resulting in significant delays;

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- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; and

- the supply or quality of our drug candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate.

In addition, the current standard of care for the treatment of HCV is a protease inhibitor such as telaprevir (Incivek®), boceprevir (Victrelis®) or simeprevir (Olysio) in combination with P/R. If the current standard of care changes, for example due to the approval by the FDA of new classes of compounds that provide better safety or efficacy such as has been demonstrated by nucleotide polymerase inhibitor sofosbuvir (Sovaldi), then we could be required to carry out more extensive studies, evaluate different treatment combinations or complete comparative effectiveness studies, resulting in significant delays and/or increased costs.

We, and a number of other companies in the pharmaceutical and biotechnology industries, have suffered significant setbacks in later stage clinical trials even after achieving promising results in early-stage development. For example, in June 2013, the FDA placed a full clinical hold on sovaprevir that was not released until June 2014, during which time we suffered a significant decline in share price.

Expenses associated with clinical trials may cause our earnings to fluctuate, which could adversely affect our stock price.

The clinical trials required for regulatory approval of our products, as well as clinical trials we are required to conduct after approval, are very expensive. It is difficult to accurately predict or control the amount or timing of these expenses from quarter to quarter, and the FDA and/or other regulatory agencies may require more clinical testing and analysis than we originally anticipated for our drug candidates. Uneven and unexpected spending on these programs may cause our operating results to fluctuate from quarter to quarter, and our stock price may decline.

If we are unable to obtain U.S. and/or foreign regulatory approval, we will be unable to commercialize our drug candidates.

Our drug candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, record keeping, labeling, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required in the United States and in many foreign jurisdictions prior to the commercial sale of our drug candidates. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the drug candidates we are developing will obtain marketing approval. In connection with the clinical trials for ACH-3422, ACH-3102, sovaprevir, and any other drug candidate we may seek to develop in the future, we face risks that:

- the drug candidate may not prove to be efficacious;

- the drug candidate may not prove to be safe;

- the results may not confirm the positive results from earlier preclinical studies or clinical trials;

the results may not meet the level of statistical significance required by the FDA or other regulatory agencies; and

the FDA or other regulatory agencies may require us to carry out additional studies.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to complete clinical trials and for the FDA and other countries regulatory review processes is uncertain and typically takes many years. Our analysis of data obtained from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unanticipated delays or increased costs due to government regulation from future legislation or administrative action or changes in FDA policy during the period of product development, clinical trials, and FDA regulatory review.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to progress the development of a drug candidate and to generate revenues from that drug candidate. For example, in June 2013, the FDA placed a full clinical hold on sovaprevir that was not released until June 2014.

Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product and affect reimbursement by third-party payors. These limitations may limit the size of the market for the product. We are also subject to numerous foreign regulatory requirements governing the conduct of clinical trials, manufacturing and marketing

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authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of foreign regulations. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval procedures than those required by the FDA and may impose additional testing requirements for our drug candidates.

If clinical trials for our drug candidates are prolonged or delayed, we may be unable to commercialize our drug candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.

We cannot predict whether we will encounter problems with any of our completed, ongoing or planned clinical trials that will cause us or regulatory authorities to delay, suspend or terminate clinical trials, or delay the analysis of data from our completed or ongoing clinical trials.

Further, we cannot predict whether or how program discontinuations by competitors (such as the discontinuation in 2012 by Bristol-Myers Squibb of BMS-986094, a nucleotide polymerase inhibitor, due to serious cardiac-related adverse events) may increase the level of scrutiny by the FDA on our drug candidates, slowing data review and response times or otherwise creating delays or difficulties in initiating and progressing clinical trials. We also cannot predict the degree to which new therapies from competitors, like nucleotide polymerase inhibitor sofosbuvir (Sovaldi), will increase the rigor the FDA applies in its review of subsequent therapies. In addition, in October 2013, the FDA s Center for Drug Evaluation and Research, or CDER, issued for comment new guidelines on the development of DAAs for the treatment of chronic HCV entitled Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment. While such guidelines were issued only for comment and are not authoritative, the guidelines indicate that there is less certainty around the FDA s expectations for clinical development of DAAs for the treatment of HCV and the extent of preclinical and clinical trials, including required clinical comparators that are necessary for registration and approval of a drug candidate.

Any of the following could delay the clinical development of our drug candidates:

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in receiving, or the inability to obtain, required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling volunteers and patients into clinical trials;
- a lower than anticipated retention rate of volunteers and patients in clinical trials;
- delays in gathering and interpreting clinical data;

- the need to repeat clinical trials as a result of inconclusive or negative results or unforeseen complications in testing;

- the placement by the FDA of a clinical hold or partial clinical hold on a trial, such as the clinical hold placed on sovaprevir from June 2013 until June 2014 and the partial clinical hold currently on sovaprevir for multiple dose studies in healthy volunteers;

- the requirement by the FDA, in connection with future HCV development guidelines recently circulated for comment, to carry out additional studies;

- delays in completing formulation development of our drug candidates, or delays in planning and executing the bridging studies required to use the new formulations in subsequent clinical trials;

- inadequate supply or deficient quality of drug candidate materials or other materials necessary to conduct our clinical trials;

- unfavorable FDA inspection and review of a clinical trial site or records of any clinical or preclinical investigation; or

- serious and unexpected drug-related side effects experienced by participants in our clinical trials or in third-party clinical trials of similar HCV drug candidates.

Our ability to enroll patients in our clinical trials in sufficient numbers and on a timely basis will be subject to a number of factors, including the size of the patient population, the nature of the protocol, the existence of clinical trials for competing drugs also in clinical development, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial. Delays in patient enrollment may result in increased costs and longer development times. We currently face competition for subjects to enroll in our clinical trials and may have to expand the number of sites at which the trials are conducted. If we are not successful in doing so, the planned timing for release of data from these trials may not be achieved. In addition, subjects may drop out of our clinical trials, and thereby impair the validity or statistical significance of the trials.

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We, the FDA or other applicable regulatory authorities may suspend clinical trials of a drug candidate at any time if we or they believe the subjects or patients participating in such clinical trials are being exposed to unacceptable health risks or for other reasons. For example, in June 2013, the FDA placed a full clinical hold on sovaprevir after elevations in liver enzymes were noted in a phase I healthy subject drug-drug interaction study evaluating the effects of concomitant administration of sovaprevir with ritonavir-boosted atazanavir. Such hold was lifted in June 2014, allowing us to continue dosing sovaprevir in HCV-infected subjects. Additionally, when we advanced sovaprevir into longer term clinical trials in phase II, we established predetermined stopping rules, as well as a Data Safety Monitoring Board, or DSMB, in order to monitor and ensure patient safety. Any interruption of these clinical trials, whether as a result of one of our drug candidates, or of co-administration of a concomitant anti-HCV agent, or of administrative review delays on the part of the DSMB or FDA, could cause delays in our drug development.

We cannot predict whether any of our drug candidates will encounter problems during clinical trials which will cause us or regulatory authorities to delay or suspend these trials, or which will delay the analysis of data from these trials. In addition, it is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. If we experience any such problems, we may not have the financial resources to continue development of the drug candidate that is affected or the development of any of our other drug candidates.

In addition, we, along with our collaborators or subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA s Application Integrity Policy. Employment of such a debarred person (even if inadvertently) may result in delays in the FDA s review or approval of our products, or the rejection of data developed with the involvement of such persons.

Fast Track designation does not guarantee approval, or expedited approval, of ACH-3102 or sovaprevir and there is no guarantee that ACH-3102 or sovaprevir will maintain Fast Track designation.

In December 2011 and May 2012, we announced that the FDA granted Fast Track designation to sovaprevir and ACH-3102, respectively, for the treatment of HCV. Under the FDA Modernization Act of 1997, Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions. Compounds selected must demonstrate the potential to address an unmet medical need for such a condition. Mechanisms intended to facilitate development include opportunities for frequent dialogue with FDA reviewers and for timely review of submitted protocols. However, the designation does not guarantee approval or expedited approval of any application for the product. Furthermore, the FDA may revoke Fast Track designation from a product candidate at any time if it determines that the criteria are no longer met.

Even if we obtain regulatory approvals, our drug candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals, and our business would be seriously harmed.

Even if we receive regulatory approval of any drugs we are developing or may develop, we will be subject to continuing regulatory review, including the review of clinical results which are reported after our drug candidates become commercially available approved drugs. As greater numbers of patients use a drug following its approval, side effects and other problems may be observed after approval that were not seen or anticipated during pre-approval clinical trials. In addition, the manufacturer, and the manufacturing facilities we use to make any approved drugs, will also be subject to periodic review and inspection by the FDA.

The subsequent discovery of previously unknown problems with the drug, manufacturer or facility may result in restrictions on the drug, manufacturer or facility, including withdrawal of the drug from the market. If we fail to

comply with applicable continuing regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approval, product recalls and seizures, operating restrictions and criminal prosecutions. Our product promotion and advertising is also subject to regulatory requirements and continuing regulatory review. In particular, the marketing claims we will be permitted to make in labeling or advertising regarding our marketed products will be limited by the terms and conditions of the FDA-approved labeling. We must submit copies of our advertisements and promotional labeling to the FDA at the time of initial publication or dissemination. If the FDA believes these materials or statements promote our products for unapproved indications, or with unsubstantiated claims, or if we fail to provide appropriate safety-related information, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue a warning letter, which may demand, among other things, that we cease such promotional activities and issue corrective advertisements and labeling. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. Moreover, the Department of Justice can bring civil or criminal actions against companies that promote drugs or biologics for unapproved uses, based on the False Claims Act and other federal laws governing reimbursement for such products under the Medicare, Medicaid and other federally supported healthcare programs. Monetary penalties in such cases have often been substantial, and civil penalties can include costly mandatory compliance programs and exclusion from federal healthcare programs.

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If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development efforts involve the controlled use of hazardous materials, chemicals and various radioactive compounds. Although we believe that our safety procedures for the use, manufacture, storage, handling and disposing of these materials comply with the standards prescribed by federal, state and local laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials.

Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. Although we maintain workers compensation insurance to cover us for costs we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. In addition, though we have environmental liability insurance, such coverage may not provide for all related losses. We may incur substantial costs to comply with, and substantial fines or penalties, if we violate any of these laws or regulations.

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a process that requires the submission of a clinical trial application much like an investigational new drug application prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application, or CTA, must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country s requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with good clinical practices, or GCPs, and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union, or E.U., regulatory systems, we must submit a marketing authorization application. This application is similar to the NDA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the E.U. by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the E.U. This procedure results in a single marketing authorization granted by the European Commission that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for certain human drugs including those that are: (i) derived from biotechnology processes, such as genetic engineering or (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases.

Market exclusivity provisions under the Federal Food, Drug and Cosmetic Act can delay the submission or the approval of certain applications.

The Federal Food, Drug and Cosmetic Act, or FDCA, provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent.

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Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Risks Related to Our Dependence on Third Parties

We may not be able to execute our business strategy if we are unable to enter into alliances with other companies that can provide capabilities and funds for the development and commercialization of our drug candidates. If we are unsuccessful in forming or maintaining these alliances on favorable terms, our business may not succeed.

We may consider forming exclusive or non-exclusive alliances with major biotechnology or pharmaceutical companies to jointly develop, and commercialize if approved, our NS5A inhibitor candidates, our nucleotide polymerase inhibitor candidates and/or our protease inhibitor candidates. In such alliances, we would expect our biotechnology or pharmaceutical collaborators to provide substantial funding, as well as significant capabilities in clinical development, regulatory affairs, marketing and sales. We may not be successful in entering into any such alliances on favorable terms or in a timely manner, if at all. There are a limited number of collaboration partners whose pipeline of HCV clinical candidates are suitable for co-development with ours. There are also a limited number of potential collaboration partners without a robust HCV drug candidate pipeline, but demonstrated commercial interest in HCV therapeutics who may have interest in gaining rights to our HCV drug candidates. Recent consolidation may have reduced the number of potential partners further making achieving a suitable partnership more difficult, potentially limiting our ability to command a significant premium in any such transaction. Further, if potential collaboration partners enter alliances with other competing HCV companies, our future business prospects may be harmed, as these alliances could reduce the pool of potential partners for our compounds and/or limit the value of such alliance.

Even if we do succeed in securing such alliances, we may not be able to maintain them if development or approval of a drug candidate is delayed or sales of an approved drug are disappointing. For example, a 2004 license and collaboration agreement between us and Gilead for the advancement of certain HCV compounds operating by the mechanism of action known as NS4A antagonism was terminated in February 2012 as neither party was devoting significant time to advancing the compounds under the agreement. Furthermore, any delay in entering into collaboration agreements could delay the development and commercialization of our drug candidates and reduce their competitiveness even if they reach the market. Any such delay related to our collaborations could adversely affect our business.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet established deadlines for the completion of such trials.

We rely on third parties such as contract research organizations, medical institutions and clinical investigators to enroll qualified patients and conduct our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities. These third-party contractors may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our trial design. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial. Accordingly, our efforts to obtain regulatory approvals for and commercialize our drug candidates may be delayed.

We currently depend on third-party manufacturers to produce our preclinical and clinical drug supplies and intend to rely upon third-party manufacturers to produce commercial supplies of any approved drug candidates. We also depend on third parties to assist us in developing appropriate formulations of our drug candidates. If, in the future, we manufacture any of our drug candidates, we will be required to incur significant costs and devote significant efforts to establish and maintain these capabilities.

We rely upon third parties to produce material for preclinical and clinical testing purposes and intend to continue to do so in the future. We also depend on third parties to assist us in developing appropriate formulations of our drug candidates. We also expect to rely upon third parties to produce materials required for the commercial production of our drug candidates if we succeed in obtaining necessary regulatory approvals. If we are unable to arrange for third-party manufacturing, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them. Further, if third parties are not successful in formulation development of our drug candidates, our development timelines may be delayed. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our

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drug candidates be manufactured according to current good manufacturing practice regulations. Any failure by us or our third-party manufacturers to comply with current good manufacturing practices and/or our failure to scale up our manufacturing processes could lead to a delay in, or failure to obtain, regulatory approval of any of our drug candidates. In addition, such failure could be the basis for action by the FDA to withdraw approvals for drug candidates previously granted to us and for other regulatory action.

To date, our third-party formulators and manufacturers have met our formulation and manufacturing requirements, but we cannot be assured that they will continue to do so. Any performance failure on the part of our existing or future formulators or manufacturers could delay clinical development or regulatory approval of our drug candidates or commercialization of any approved products. If for some reason our current contractors cannot perform as agreed, we may be required to replace them. Although we believe that there are a number of potential replacements given our formulation and manufacturing processes are not contractor specific, we may incur added costs and delays in identifying and qualifying any such replacements. Furthermore, although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a drug candidate to complete the trial, any significant delay in the supply of a drug candidate for an ongoing trial due to the need to replace a third-party manufacturer could delay completion of the trial.

We may in the future elect to manufacture certain of our drug candidates in our own manufacturing facilities. If we do so, we will require substantial additional funds and need to recruit qualified personnel in order to build or lease and operate any manufacturing facilities.

Risks Related to Commercialization of Our Drug Candidates

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, we may not generate product revenue.

We have no commercial products, and we do not currently have an organization for the sales and marketing of pharmaceutical products. In order to successfully commercialize any drugs that may be approved in the future by the FDA or comparable foreign regulatory authorities, we must build our sales and marketing capabilities or make arrangements with third parties to perform these services. For certain drug candidates in selected indications where we believe that an approved product could be commercialized by a specialty North American sales force that calls on a limited but focused group of physicians, we may commercialize these products ourselves. However, in therapeutic indications that require a large sales force selling to a large and diverse prescribing population and for markets outside of North America, we may enter into arrangements with other companies for commercialization. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable.

The development of directly acting antivirals to treat HCV, and the potential changes in market dynamics that may result from their introduction for HCV therapy, may present additional risks beyond those inherent in drug development.

We are developing multiple DAA compounds, in three distinct classes, for treatment of HCV. Other companies are also developing DAAs in these classes, as well as other classes. Until the recent introduction of DAA therapy, the standard of care for HCV infection included therapy with pegylated interferon and ribavirin. Four DAAs developed by our competitors, telaprevir (Incivek®) by Vertex, boceprevir (Victrelis®) by Merck, simeprevir (Olysio) by Johnson and Johnson and sofosbuvir (Sovaldi) by Gilead, were recently approved by the FDA for use in combination with P/R, and recently became a new standard of care for genotype 1 HCV (in the case of telaprevir, boceprevir and simeprevir) and for genotype 2/3 in the case of sofosbuvir. We cannot currently predict when or if additional compounds currently

in development may again change the standard of care in the future.

The development plans for our compounds include treatment regimens with our inhibitors in combination with another DAA, or our inhibitors with one or more DAAs with or without concomitant ribavirin therapy. These development programs carry all the risks inherent in drug development activities, including the risk that they will fail to show efficacy or acceptable safety, as well as the risk that a safety issue related to one compound may negatively impact another compound with which it is dosed. In addition, these development programs may also be subject to additional regulatory, commercial and manufacturing risks that may be additional to the risks inherent in drug development activities.

Regulatory guidelines for approval of DAA drugs for the treatment of HCV are evolving in the United States, Europe, and other countries. We anticipate that regulatory guidelines and regulatory agency responses to our and our competitors development programs will continue to change, resulting in the risk that our activities may not meet unanticipated new standards or requirements, which could lead to delay, additional expense, or potential failure of development activities.

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Furthermore, even if we or our competitors successfully develop DAAs whose use improves the current standard of care, current HCV-treating physicians, HCV patients, healthcare payers, and others may not readily accept or pay for such improvements or new treatments. In addition, because development of DAAs for HCV infection is an emerging field, the delay or failure of a competitor attempting to develop therapeutics that could have been combined with our product candidates or that are perceived to be similar to our product candidates could have a significant adverse effect on the commercial or regulatory environment for our product candidates or on the price of our stock. Other companies developing DAAs have more advanced development programs than we do. Their success or failure to successfully conclude clinical development and obtain marketing approval could have a material adverse effect on our development and commercialization plans and activities.

If our future drugs do not achieve market acceptance, we may be unable to generate significant revenue, if any.

Even if ACH-3422, ACH-3102, sovaprevir, or any other drug candidates we may develop or acquire in the future obtain regulatory approval, they may not gain market acceptance among physicians, health care payors, patients and the medical community. Factors that we believe could materially affect market acceptance of our product candidates include:

- the timing of market introduction of competitive drugs;
- the demonstrated clinical safety and efficacy of our product candidates compared to other drugs and other drug candidates;
- the suitability of our drug candidates to be co-administered or combined with other drugs or drug candidates;
- the durability of our drug candidates in their ability to prevent the emergence of drug-resistant viral mutants;
- the convenience and ease of administration of our product candidates;
- the existence, prevalence and severity of adverse side effects;
- other potential advantages of alternative treatment methods;
- the effectiveness of marketing and distribution support;
- the cost-effectiveness of our product candidates; and
- the availability of reimbursement from managed care plans, the government and other third-party payors.

If our approved drugs fail to achieve market acceptance, we would not be able to generate significant revenue.

If third-party payors do not adequately reimburse patients for any of our drug candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend significantly upon the availability of adequate reimbursement for the use of any approved drug candidates from governmental and other third-party payors, both in the United States and in foreign markets. Reimbursement by a third party may depend upon a number of factors, including the third-party payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost effective; and

neither experimental nor investigational.

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Obtaining reimbursement approval for a product from each third-party and government payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of any approved drugs to each payor. We may not be able to provide data sufficient to gain acceptance with respect to reimbursement. There also exists substantial uncertainty concerning third-party reimbursement for the use of any drug candidate incorporating new technology, and even if determined eligible, coverage may be more limited than the purposes for which the drug is approved by the FDA. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Interim payments for new products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost products or combinations of products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

Further, we may face future challenges from payors as new HCV drug approvals such as sofosbuvir (Sovaldi) have relatively high cost per course of treatment. For example, Sovaldi is currently priced at approximately $84,000 per 12 week treatment course, or $1,000 per daily dose.

In the United States, at both the federal and state levels, the government regularly proposes legislation to reform health care and its cost, and such proposals have received increasing political attention. In 2010, Congress recently passed legislation to reform the U.S. health care system by expanding health insurance coverage, reducing health care costs and making other changes. While health care reform may increase the number of patients who have insurance coverage for the use of any approved drug candidate, it may also include changes that adversely affect reimbursement for approved drug candidates. In addition, there has been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for any of our approved products. The Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates and may have sufficient market power to demand significant price reductions. As a result of actions by these third-party payors, the health care industry is experiencing a trend toward containing or reducing costs through various means, including lowering reimbursement rates, limiting therapeutic class coverage and negotiating reduced payment schedules with service providers for drug products.

Our inability to promptly obtain coverage and profitable reimbursement rates from government-funded and private payors for any approved products could have a material adverse effect on our operating results and our overall financial condition.

Growing availability of specialty and orphan pharmaceuticals may lead to increased focus on cost containment.

Specialty pharmaceuticals refer to drugs that are generally complex to manufacture, can be difficult to administer, and may require specialty distribution and special patient monitoring. Orphan pharmaceuticals refer to medicines that treat rare or life-threatening conditions that have smaller patient populations, such as certain types of cancer. The growing availability and use of specialty and orphan pharmaceuticals, combined with their relative higher cost as compared to other types of pharmaceutical products, is beginning to generate significant payer interest in developing cost containment strategies targeted to this sector. While the impact on our payers efforts to control access and pricing of specialty and orphan pharmaceuticals has been limited to date, the increasing use of health technology assessment in

markets around the world and the deteriorating finances of governments, may lead to a more significant adverse business impact on drug pricing in the future.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic and diagnostic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

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Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Patents and Licenses

If our patent position does not adequately protect our drug candidates, others could compete against us more directly, which would harm our business.

We own or hold exclusive licenses to several issued patents U.S. and pending U.S. provisional and non-provisional patent applications, as well as pending PCT applications and associated non-US patents and patent applications. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our drug candidates. Our ability to protect our drug candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our drug candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be valid or enforceable or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us. Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office, which we refer to as the U.S. Patent Office, for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors or co-owners were the first to invent, or the first to file patent applications on, our drug candidates or their use as anti-infective drugs. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

The HCV inhibitor space is particularly crowded in terms of intellectual property, and certain competitors such as Alios, AstraZeneca, Bayer, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Merck, Novartis and Vertex have disclosed compounds that may be prior art to our patent applications and prevent issuance or alter the scope of any claims that we may pursue related to our drug candidates.

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The claims of the issued patents that are licensed to us, and the claims of any patents which may issue in the future and be owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents. Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, the issued patents relating to our drug candidates may be limited to a particular molecule. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different molecule, our patents may not prevent others from directly competing with us.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our drug candidates, thereby reducing any advantages of the patent. To the extent our drug candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such product candidates, those drug candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug and Cosmetic Act or trade secret protection.

The Leahy-Smith America Invents Act, or the America Invents Act, was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act reforms United States patent law in part by changing the standard for patent approval from a first to invent standard to a first to file standard and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 2013.

We license patent rights from third-party owners. If such owners do not properly maintain or enforce the patents underlying such licenses, our competitive position and business prospects will be harmed.

We are party to a number of licenses that give us rights to third-party intellectual property that is necessary or useful for our business. In particular, we have obtained licenses from Yale University and Emory University with respect to elvucitabine. We may enter into additional licenses for third-party intellectual property in the future. Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents issue in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. In addition, our licensors may terminate their agreements with us in the event we breach the applicable license agreement and fail to cure the breach within a specified period of time. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

Because our research and development of drug candidates incorporates compounds and other information that is the intellectual property of third parties, we depend on continued access to such intellectual property to conduct and

complete our preclinical and clinical research and commercialize the drug candidates that result from this research. Some of our existing licenses impose, and we expect that future licenses would impose, numerous obligations on us. For example, under our existing and future license agreements, we may be required to pay minimum annual royalty amounts and/or payments upon the achievement of specified milestones. We may also be required to reimburse patent costs incurred by the licensor, or we may be obligated to pay additional royalties, at specified rates, based on net sales of our product candidates that incorporate the licensed intellectual property rights. We may also be obligated under some of these agreements to pay a percentage of any future sublicensing revenues that we may receive. Future license agreements may also include payment obligations such as milestone payments or minimum expenditures for research and development. In addition to our payment obligations under our current licenses, we are required to comply with reporting, insurance and indemnification requirements under the agreements. We expect that any future licenses would contain similar requirements.

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If we fail to comply with these obligations or otherwise breach a license agreement, the licensor may have the right to terminate the license in whole, terminate the exclusive nature of the license or bring a claim against us for damages. Any such termination or claim could prevent or impede our ability to market any drug that is covered by the licensed intellectual property. Even if we contest any such termination or claim and are ultimately successful, our financial results and stock price could suffer. In addition, upon any termination of a license agreement, we may be required to grant to the licensor a license to any related intellectual property that we developed. For example, the licensors have the right to terminate our license of the intellectual property covered by its licenses to us under certain circumstances, including our failure to make payments to the licensor when due and our uncured breach of any other terms of the licenses. If access to such intellectual property is terminated, or becomes more expensive as a result of renegotiation of any of our existing license agreements, our ability to continue development of our product candidates or the successful commercialization of our drug candidates could be severely compromised and our business could be adversely affected.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development and commercialization activities, including any drug candidates resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. There may be applications that have been filed but not published that, if issued, could be asserted against us. We are aware that certain third parties, including Alios, AstraZeneca, Bayer, Bristol-Myers Squibb, Enanta, Gilead, GlaxoSmithKline, Idenix, Merck, Novartis and Vertex have applications that are directed to certain classes of HCV inhibitors, including synthetic nucleotides. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or drug candidate that is the subject of the suit. Further, if we are found to have infringed a third-party patent, we could be obligated to pay royalties and/or other payments to the third party for the sale of our product, which may be substantial, or we could be enjoined from selling our product.

For example, we are aware that litigation has been instituted between Merck and Gilead, as well as Idenix and Gilead, wherein each of Merck and Idenix have asserted that Gilead s commercialization of Sovaldi (sofosbuvir), a nucleotide analog polymerase inhibitor, for the treatment of chronic hepatitis C would infringe certain patents owned by Merck and certain patents co-owned by Idenix. Given the heightened litigation environment around Sovaldi , it follows that the commercialization of ACH-3422, which is also a uridine nucleotide prodrug, may be subject to similar infringement challenges by Merck, Idenix and/or other companies.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U. S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our product candidates and technology. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Litigation regarding patents, intellectual property, and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing drug candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of intellectual

property infringement related to our drug candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Under our license agreements with Yale University we have the right, but not an obligation, to bring actions against an infringing third party. If we do not bring an action within a specified number of days, the licensor may bring an action against the infringing party. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

the patentability of our inventions relating to our drug candidates; and/or

the enforceability, validity or scope of protection offered by our patents relating to our drug candidates.

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Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our drug candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our drug candidates or methods of treatment requiring licenses.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Because of the relative weakness of the Chinese and Indian legal systems in general, and intellectual property rights in particular, we may not be able to enforce intellectual property rights in China and India.

The legal regime protecting intellectual property rights in China and India is weak. Because the Chinese and Indian legal systems in general, and the intellectual property regime in particular, are relatively weak, it is often difficult to create and enforce intellectual property rights in China and India. Accordingly, we may not be able to effectively protect our intellectual property rights for our compounds in China and India.

We rely on our ability to stop others from competing by enforcing our patents, however some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries, including certain countries in Asia, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

We rely on unpatented trade secrets, know-how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory

approval process. We seek to protect trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements, or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Our Securities

We may dilute our existing stockholders in connection with capital raising activities. Additionally, the market price of our common stock may fall due to the number of freely-tradable shares available in the public market.

In connection with capital raising activities, we may be required to dilute our existing stockholders substantially. For example, since August 2008, we have issued an aggregate of 76,608,269 shares of our common stock in private and registered offerings, as well as warrants to purchase an aggregate of 13,279,028 shares of our common stock. As of June 30, 2014, we have 4,530,969 warrants outstanding at a weighted average exercise price of $3.12. All of the shares of common stock we issued, as well as those shares issuable upon exercise of the warrants, are freely tradable pursuant to effective registration statements, making such shares available for immediate resale in the public market. In November 2012, we entered into a sales agreement with Cantor pursuant to which, from time to time, we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 through Cantor pursuant to an effective universal shelf registration statement that we filed in November 2012. Sales of our common stock, if any, under the agreement with Cantor may be made in sales deemed to be at-the-market equity offerings as defined in Rule 415 under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through the NASDAQ Global Select Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Sales of substantial amounts of shares of our common stock or other securities could lower the market price of our common stock.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval, which could have the effect of delaying, deferring or preventing a change in control if us and entrenching our management or board of directors.

As of August 1, 2014, our directors, executive officers and stockholders who own more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own, in the aggregate, greater than approximately 80% of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, sale of all or substantially all of our

assets or similar transaction, as well as our management and affairs. The interests of this group of stockholders may not always coincide with our corporate interests or the interest of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of voting power may have the effect of delaying, deferring or preventing a change in control of our company on terms that other stockholders may desire and entrenching our management or board or directors.

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Our stock price has been and may in the future be volatile, and the market price of our common stock may decline in value in the future.

The market price of our common stock has fluctuated in the past and is likely to fluctuate in the future. During the period from January 1, 2009 to June 30, 2014, our stock price has ranged from a low of $0.70 to a high of $12.95. Market prices for securities of early stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the results of clinical trials of our nucleotide polymerase inhibitor, ACH-3422, our NS5A inhibitor, ACH-3102, and our protease inhibitor, sovaprevir;
- further developments relating to the FDA s partial clinical hold on sovaprevir for multiple dose studies in healthy volunteers;
- the results of clinical trials conducted by others on drugs that would compete with our drug candidates;
- the announcements of those data, particularly at high profile medical meetings, and the investment community s perception of and reaction to those data;
- the ability of our drug candidates to be dosed safely in combination with other drugs and/or drug candidates, both ours and others;
- the entry into, modification of, or termination of key agreements, or any new collaboration agreement we may enter;
- market expectations about the timeliness of our entry into, or failure to enter, collaboration arrangements with third parties;
- market expectations about and response to the level of sales achieved by competitive, recently approved drugs such as sofosbuvir (Sovaldi);
- the entry by a potential third-party collaborator into an alliance with a competitor, or the entry by any other HCV drug developer into an alliance that may be perceived as competitive to us;
- the continued industry consolidation of pharmaceutical companies developing HCV drug therapies, or the acquisition of any one of our HCV drug development competitors;

the premiums on other transactions and any significant increases or decreases of those premiums;

the results of regulatory reviews and actions relating to the approval of our drug candidates;

our failure to obtain patent protection for any of our drug candidates or the issuance of third-party patents that cover our drug candidates;

the initiation of, material developments in, or conclusion of litigation;

failure of any of our drug candidates, if approved, to achieve commercial success;

general and industry-specific economic conditions that may affect our business, financial condition and operations, including without limitation research and development expenditures;

the launch of drugs by others that would compete with our drug candidates;

the failure or discontinuation of any of our research programs;

issues in manufacturing our drug candidates or any approved products;

the introduction of technological innovations or new commercial products by us or our competitors;

changes in estimates or recommendations by securities analysts, if any, who cover our common stock;

future sales of our common stock;

changes in the structure of health care payment systems;

period-to-period fluctuations in our financial results;

low trading volume of our common stock; and

the other factors described in this Risk Factors section.

In addition, if we fail to reach an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be significant impact on the market price of our common stock. Additionally, as we approach the announcement of important clinical data or other significant information and as we announce such results and information, we expect the price of our common stock to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock.

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The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation. For example, we, and certain of our current and former officers, were named as defendants in a consolidated class action lawsuit following our announcements regarding the FDA s clinical hold related to sovaprevir, our clinical-stage drug candidate for the treatment of chronic hepatitis C viral infection. On May 5, 2014, without any settlement payment by us, any individual defendant or any third party on their behalf, the lead plaintiffs in the consolidated class action lawsuit voluntarily dismissed all of their claims without prejudice. See Part II, Item 1 Legal Proceedings.

Unstable market and economic conditions may have serious adverse consequences on our business.

Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

Our management is required to devote substantial time and incur additional expense to comply with public company regulations. Our failure to comply with such regulations could subject us to public investigations, fines, enforcement actions and other sanctions by regulatory agencies and authorities and, as a result, our stock price could decline in value.

As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, as well as the rules of the NASDAQ Global Select Market, have required us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations places significant additional demands on our limited number of finance and accounting staff and on our financial, accounting and information systems.

In particular, as a public company, our management is required to conduct an annual evaluation of our internal controls over financial reporting and include a report of management on our internal controls in our annual reports on Form 10-K. If we are unable to continue to conclude that we have effective internal controls over financial reporting or, if our independent auditors are unable to provide us with an attestation and an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

We do not anticipate paying cash dividends, and accordingly stockholders must rely on stock appreciation for any return on their investment in us.

We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

ITEM 6. EXHIBITS

10.1	Letter Agreement, dated May 23, 2014, between Achillion Pharmaceuticals, Inc. and Milind Deshpande
31.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of President and Chief Executive Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.
32.2	Certification of Chief Financial Officer of Achillion Pharmaceuticals, Inc. pursuant to Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code.

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101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Label Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Balance Sheets at June 30, 2014 and December 31, 2013 (unaudited), (ii) Statements of Comprehensive Loss for the three and six months ended June 30, 2014 and 2013 (unaudited), (iii) Statements of Cash Flows for the six months ended June 30, 2014 and 2013 (unaudited), and (iv) Notes to Financial Statements (unaudited).

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACHILLION PHARMACEUTICALS, INC.

Date: August 7, 2014

/s/ Milind S. Deshpande
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2014

/s/ Mary Kay Fenton
Chief Financial Officer
(Principal Financial and Accounting Officer)

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